

Paul L. Stoller (No. 016773)  
Ashley Crowell (No. 027289)  
DALIMONTE RUEB STOLLER, LLP  
2425 East Camelback Road, Suite 500  
Phoenix, Arizona 85016  
Telephone: (602) 888-2807  
[paul@drlawllp.com](mailto:paul@drlawllp.com)  
[ashley@drlawllp.com](mailto:ashley@drlawllp.com)

Ben C. Martin (Texas Bar No. 13052400)  
(*pro hac vice application forthcoming*)  
Kolter C. McKenzie (Texas Bar No. 24067762)  
(*pro hac vice application forthcoming*)  
MARTIN BAUGHMAN, PLLC  
3141 Hood Street, Suite 600  
Dallas, Texas 75219  
(214) 761-6614  
Facsimile: (214) 744-7590  
[bmartin@martinbaughman.com](mailto:bmartin@martinbaughman.com)  
[kmckenzie@martinbaughman.com](mailto:kmckenzie@martinbaughman.com)

*Attorneys for Plaintiff*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

CONNIE ESPARZA,

Plaintiff,

v.

ETHICON ENDO-SURGERY, INC.,  
ETHICON ENDO-SURGERY, LLC,  
JOHNSON & JOHNSON HEALTH CARE  
SYSTEMS, INC., and  
JOHNSON & JOHNSON CONSUMER,  
INC.,

Defendants.

Case No.

**COMPLAINT**

**(JURY TRIAL DEMANDED)**

COMES NOW, Connie Esparza, Plaintiff, (hereinafter referred to as “Plaintiff” or  
“Esparza”) complaining of Defendants, Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery,

1 LLC, Johnson & Johnson Health Care Systems, Inc. and Johnson & Johnson Consumer,  
 2 Inc., (hereinafter referred to as “Defendants”), and would respectfully show unto the Court  
 3 as follows:

## 4 **I. INTRODUCTION**

5 1.1 Defendants, and each of them, designed, manufactured, and marketed without  
 6 proper notice, defective Ethicon Endo-Surgery Staplers. The FDA recently reported that  
 7 during the time period from January 1, 2011, through December 31, 2018, it received close  
 8 to 110,000 reports related to issues with surgical staplers. Of these, 412 were submitted as  
 9 deaths, 11,181 were submitted as serious injuries, and 98,404 were submitted as  
 10 malfunctions.<sup>1</sup>

11 1.2 Plaintiff Connie Esparza was injured when a surgical stapler, designed,  
 12 manufactured, and marketed by Defendants, malfunctioned during her November 19, 2019,  
 13 surgery, resulting in a leak in her abdomen that had to be repaired through a series of  
 14 subsequent surgeries.

## 15 **II. PARTIES**

16 2.1. At all times material, Plaintiff Connie Esparza was an individual residing in  
 17 the State of Arizona.

18 2.2 At all times material, Defendant Ethicon Endo-Surgery, Inc., was and is an  
 19 Ohio corporation with its principal place of business at 4545 Creek Road, Mail Location  
 20 11, Cincinnati, Ohio 45242. At all times material, Defendant Ethicon Endo-Surgery, Inc.,  
 21 has been conducting business throughout the State of Arizona and maintains significant,  
 22 systematic and continuous contacts throughout the State of Arizona, but does not appear to  
 23 have a designated agent within the state upon whom service of process may be had for  
 24 causes of action arising out of such business.

25 2.3 At all times material, Defendant Ethicon Endo-Surgery, LLC, is incorporated  
 26 in the State of Delaware and its principal place of business is located in Puerto Rico and,

---

27 <sup>1</sup> FDA Executive Summary Prepared for the May 30, 2019, Meeting of the General and  
 28 Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use:  
<https://www.fda.gov/media/126211/download>

per its Certificate of Authorization to do Business of a Foreign Corporation filed with the Puerto Rico Registry of Corporations and Entities, lists its designated office address in Puerto Rico as 475 Street C Los Frailes Industrial Park, Suite 401, Guaynabo, PR 00969 and its Corporate Domicile as 1209 Orange Street, Wilmington, DE 19801. According to Ethicon Endo-Surgery's registration with the Registry of Corporations and Entities in Puerto Rico, the LLC has twenty Administrators, domiciled in Puerto Rico (8), New Jersey (6), and Ohio (6). No members are domiciled in the State of Arizona. A copy of the registration is attached as Exhibit "A." At all times material, Defendant Ethicon Endo-Surgery, LLC, has been conducting business throughout the State of Arizona and maintains significant, systematic and continuous contacts throughout the State of Arizona, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.4 At all times material, Defendant Johnson & Johnson Health Care Systems, Inc., ("Johnson & Johnson") was and is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Johnson & Johnson can be served with process through its Chief Executive Officer, Alex Gorsky, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material, Johnson & Johnson has been conducting business throughout the State of Arizona and maintains significant, systematic and continuous contacts throughout the State of Arizona, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.5 At all times material, Defendant Johnson & Johnson Consumer, Inc., ("Johnson & Johnson Consumer") was and is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Johnson & Johnson Consumer can be served with process through its Chief Executive Officer, Alex Gorsky, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material, Defendant Johnson & Johnson Consumer, Inc. has been conducting business throughout the State of Arizona and maintains significant, systematic

1 and continuous contacts throughout the State of Arizona, but does not appear to have a  
 2 designated agent within the state upon whom service of process may be had for causes of  
 3 action arising out of such business.

4 2.6 Defendants Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery, LLC,  
 5 Johnson & Johnson Health Care Systems, Inc., and Johnson & Johnson Consumer, Inc.,  
 6 shall be referred to herein individually by name or jointly as the “Ethicon Defendants.”

### 7 **III. JURISDICTION AND VENUE**

8 3.1 The Court has jurisdiction over this civil action pursuant to 28 U.S.C. §  
 9 1332(a) inasmuch as the amount in controversy exceeds \$75,000, exclusive of interests and  
 10 costs, and Plaintiff is a citizen of a different state than one or more of Defendants.

11 3.2 Venue in this district for pretrial proceedings in these civil actions is proper  
 12 under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving  
 13 rise to the claim occurred in this district.

14 3.3 At all times material, Ethicon Endo-Surgery, Inc., has been in the business of  
 15 the researching, developing, selling, and marketing of surgical staplers and staples. At all  
 16 times material, Ethicon Endo-Surgery, Inc., has been in the business of and did design,  
 17 research, manufacture, test, advertise, promote, market, sell, and distribute the surgical  
 18 stapler and staples that make the basis of this suit in the State of Arizona. This Court has  
 19 personal jurisdiction over Ethicon Endo-Surgery, Inc., because Defendant has submitted  
 20 itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in  
 21 the State of Arizona.

22 3.4 At all times material, Ethicon Endo-Surgery, LLC, has been in the business  
 23 of the researching, developing, selling, and marketing of surgical staplers and staples. At  
 24 all times material, Ethicon Endo-Surgery, LLC, has been in the business of and did design,  
 25 research, manufacture, test, advertise, promote, market, sell, and distribute the surgical  
 26 stapler and staples that make the basis of this suit in the State of Arizona. This Court has  
 27 personal jurisdiction over Ethicon Endo-Surgery, LLC, because Defendant has submitted  
 28

1 itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in  
2 the State of Arizona.

3       3.5 At all times material, Johnson & Johnson Health Care Systems, Inc., has been  
4 in the business of the researching, developing, selling, and marketing of surgical staplers  
5 and staples. At all times material, Johnson & Johnson Health Care Systems, Inc., has been  
6 in the business of and did design, research, manufacture, test, advertise, promote, market,  
7 sell, and distribute the surgical stapler and staples that make the basis of this suit in the State  
8 of Arizona. This Court has personal jurisdiction over Johnson & Johnson Health Care  
9 Systems, Inc., because Defendant has submitted itself to the jurisdiction of this Court by  
10 engaging in conduct set forth in this Complaint in the State of Arizona.

11       3.6 At all times material, Johnson & Johnson Consumer, Inc., has been in the  
12 business of the researching, developing, selling, and marketing of surgical staplers and  
13 staples. At all times material, Johnson & Johnson Consumer, Inc., has been in the business  
14 of and did design, research, manufacture, test, advertise, promote, market, sell, and  
15 distribute the surgical stapler and staples that make the basis of this suit in the State of  
16 Arizona. This Court has personal jurisdiction over Johnson & Johnson Consumer, Inc.,  
17 because Defendant has submitted itself to the jurisdiction of this Court by engaging in  
18 conduct set forth in this Complaint in the State of Arizona.

19       3.7 The Ethicon Defendants are individually, jointly, and severally liable to  
20 Plaintiff for damages suffered by Plaintiff arising from their design, manufacturing,  
21 marketing, labeling, distribution, sale, and placement of the defective product at issue in  
22 this suit. All acts were effectuated directly and indirectly through Defendants' respective  
23 agents, servants, employees, and/or owners, acting within the course and scope of their  
24 representative agencies, services, employments, and/or ownership.

25       3.8 Defendants are vicariously liable for the acts and/or omissions of their  
26 employees and/or agents, who were at all times relevant acting on Defendants' behalf and  
27 within the scope of their employment or agency with Defendants.

#### **IV. FACTS**

4.1 On November 19, 2019, Plaintiff Connie Esparza underwent a laparoscopic longitudinal sleeve gastrectomy procedure performed by Dr. Candace Jensen at Yuma Regional Medical Center. Dr. Jensen noted in part in the operative report, “The stomach was stapled and divided alongside the tube in a vertical fashion towards the angle of His, (Sic) taking care to avoid division of crows foot vessels. An Ethicon powered stapler and 1 black4/ green 60mm Gore bioseamguard reinforced staple fires were used. The stomach was removed from the abdomen via the 15 mm trocar, passed off the field as surgical specimen. 2 clips were placed at the uppermost staple line, and two at the distal staple line.”

4.2 Dr. Jensen further noted in her operative report in part, “The bougie was removed and intraoperative endoscopy was performed. There were no areas of stenosis, internal staple line bleeding, nor staple malformation or leak seen.”

4.3 Dr. Jensen also noted in her operative report in part, “The patient tolerated the procedure well, was extubated, and transferred using a Hovermatt transfer device to the post anesthesia care unit in stable and satisfactory condition.” Plaintiff’s postoperative course was unremarkable, and Plaintiff was discharged on November 21, 2019.

4.4 On November 28, 2019, Plaintiff presented to the emergency room at Yuma Regional Medical Center complaining of intense abdominal pain radiating to her back that worsened when breathing. Plaintiff also complained that her pain was an eight of ten and was so intense it caused her to have a syncopal episode prior to her arrival at the emergency room. She was admitted and placed on an IV and administered medication to control her pain. The emergency room physician suspected she might be suffering from a postoperative leak and ordered a CT scan of her pelvis and abdomen which findings were consistent with a postoperative leak related to the gastric sleeve procedure performed by Dr. Jensen on November 19, 2019. Plaintiff was also given intravenous steroids due to suspected peritonitis. A surgery consultation was requested by the emergency room physician and after the surgeon, Dr. Margaret Kunes, evaluated Plaintiff, she recommended that gastroenterology perform a procedure to place a stent over the distal esophagus and

1 proximal stomach where the leak was present. After Dr. Kunes consulted with  
2 gastroenterology, they determined it would be in the Plaintiff's best interest to be transferred  
3 to a higher level of care that specialized in handling postoperative sleeve gastrectomy leak  
4 complications due to the severity of her condition.

5 4.5. Dr. Kunes contacted Dr. Christine Lovato, a bariatric surgeon at Banner  
6 University Medical Center in Phoenix, and after explaining the circumstances requested,  
7 they accept transfer of Plaintiff's care. Dr. Lovato agreed to accept care of Plaintiff and  
8 Plaintiff was transferred to Banner University Medical Center in Phoenix by helicopter on  
9 the evening of November 28, 2019.

10 4.6 After being transported to Banner Medical Center, Plaintiff was started on  
11 intravenous steroids and a CT scan of her abdomen was ordered which revealed a proximal  
12 sleeve leak with evidence of fluid leak coming from the gastric sleeve. On December 3,  
13 2019, Plaintiff underwent a CT guided abdominal abscess drainage and catheter placement.  
14 On December 9, 2019, Plaintiff underwent an upper gastronomy endoscopy which  
15 discovered a 20mm perforation located at seven o'clock cardia position just distal to the  
16 gastroesophageal ("GE") junction and two sutures were used to repair the perforation. On  
17 December 14, 2019, Plaintiff underwent an upper gastronomy endoscopy which identified  
18 a defect along the gastric sleeve where prior sutures had been made, so one additional suture  
19 was made. On December 17, 2019, Plaintiff underwent an upper gastronomy endoscopy  
20 which revealed persistent perforation at the cardia at the proximal extent of the gastric  
21 sleeve with suture material seen. On December 18, 2019, Plaintiff underwent an upper  
22 gastronomy endoscopy which revealed the perforation found at the cardia was large and the  
23 adjacent mucosal findings included congestion. It also revealed that suture material and  
24 surgical staples were found on the margin of the perforation. The suture material and  
25 surgical staples were removed with rat tooth forceps and scissors and a stent was placed.  
26 On December 21, 2019, Plaintiff underwent an upper gastronomy endoscopy which  
27 revealed the metal stent had slipped into the cardia, and it was removed with rat tooth  
28 forceps and scissors and 25mm perforation was noted in the cardia and another stent was

1 placed. On December 27, 2019, Plaintiff underwent a procedure to remove a stent from the  
 2 middle third of her esophagus. On December 27, 2019, Plaintiff had a CT scan of abdomen  
 3 performed which showed a small air fluid pocket along the proximal gastric sleeve  
 4 concerning for possible extraluminal collection and a large pleural effusion. On December  
 5 29, 2019, Plaintiff underwent a procedure to remove her percutaneous drain, which was  
 6 replaced on December 20, 2019.

7 4.7 On January 8, 2020, Plaintiff was discharged from Banner Medical Center  
 8 with instructions to keep her PICC line in place for ninety (90) days. Plaintiff also received  
 9 a prescription/order for home healthcare and physical therapy.

10 4.8 Subsequently, Plaintiff is still receiving treatment related to the injuries she  
 11 suffered in her November 19, 2019, surgery.

12 4.9 The failure of the surgical stapler and staples in Plaintiff's November 19,  
 13 2019, surgery resulted in a number of complications, including:

- 14 a) Development of sepsis;
- 15 b) multiple stent placements;
- 16 c) multiple stent removals and laparoscopic jejunostomy placement;
- 17 d) CT guided drainage of fluid and placement of a drain tube;
- 18 e) being placed on a feeding tube;
- 19 f) CT guided abdominal abscess drainage and catheter placement; and
- 20 g) ongoing care for the injuries she suffered in her November 19, 2019,  
 21 surgery.

22 4.10 Plaintiff alleges on information and belief that one of the specific staplers  
 23 used in her November 19, 2019, surgery was a model, known by Defendants, to frequently  
 24 malfunction. The surgical stapler used in Plaintiff's November 19, 2019, surgery has been  
 25 identified by Plaintiff's surgeon and the medical records as an Ethicon product code  
 26 PSEE60A. In October of 2019, the Ethicon Defendants issued a recall on a number of its  
 27 Echelon Flex Endopath Staplers, which included the stapler that was used in Plaintiff's  
 28 surgery. Ethicon issued the recalls on the Echelon Flex Endopath Staplers because some  
 devices may contain an out of specification component within the jaw of the device, which

1 could lead to malformed staples. The recall further states that if a problem with the staple  
 2 line is not recognized or is not adequately addressed, there is a potential risk of prolonged  
 3 surgery, postoperative connection (anastomotic) leak, hemorrhage, hemorrhagic shock,  
 4 additional surgical interventions, or death.

5 4.11 Plaintiff has since learned that the stapler in question was likely recalled and  
 6 that the FDA recently reported that surgical staplers, including those manufactured by  
 7 Defendants, have been responsible for tens of thousands of adverse outcomes attributed to  
 8 malfunctioning staplers.

9 4.12 Based on the number of stapler-related injuries, in May 2019, the FDA  
 10 proposed reclassifying surgical staplers for internal use from Class I to Class II (Special  
 11 Controls).<sup>2</sup>

12 4.13 Despite knowing that its Ethicon Endo-Surgery Intraluminal Staplers caused  
 13 injuries due to malfunction, Defendants, and each of them, represented and marketed the  
 14 Ethicon Endo-Surgery Intraluminal Staplers as safe and effective. Defendants, and each of  
 15 them, failed to include warnings regarding potential malfunctions that were known to them,  
 16 including the risks described in the FDA publication.<sup>3</sup>

17 4.14 Defendants intentionally engaged in the following conduct: 1) failing to  
 18 provide warnings regarding the potential for its Echelon Flex Endopath Staplers to  
 19 malfunction in a manner exactly like what occurred during Plaintiff's surgery; 2) failing to  
 20 warn and inform surgeons of the potential for its Echelon Flex Endopath Staplers to  
 21 malfunction in a manner exactly like what occurred during Plaintiff's surgery; 3) failing to  
 22 recall its defective products until 2019 when it knew earlier that Echelon Flex Endopath  
 23 Staplers were prone to malfunction. By engaging in the conduct described above,  
 24 Defendants engaged in willful, wanton, reckless, malicious behavior and/or exhibited a  
 25

26 <sup>2</sup> FDA Executive Summary Prepared for the May 30, 2019, Meeting of the General and  
 27 Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use:  
 28 <https://www.fda.gov/media/126211/download>

<sup>3</sup> *Id.* at Pg. 9.

gross indifference to, and a callous disregard for human life, the safety, and the rights of others, and more particularly, the rights, life and safety of the Plaintiff; and Defendants were motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement and cost avoidance, to the virtual exclusion of all other considerations.

## **V. PLAINTIFF'S CAUSES OF ACTION**

### **A. (STRICT LIABILITY MANUFACTURING DEFECT)**

#### **Against all Defendants**

5.1 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.2 Plaintiff was harmed by Defendants' defective Echelon Flex Endopath Staplers, which was distributed, manufactured, and sold by Defendants. Defendants' Echelon Flex Endopath Staplers contained a manufacturing and design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in staple line failure and anastomotic leak despite proper utilization by a surgeon.

5.3 On October 3, 2019, Ethicon issued an Urgent Recall Field Safety Notice to medical providers instructing them to immediately remove any Echelon Flex Endopath Staplers from their inventory and return them to Ethicon. The recall was issued in Ethicon's words because they had, "identified the possibility that some Echelon Flex Endopath Staplers may contain an out of specification anvil component within the jaw of the device. The issue could lead to malformed staples and compromised staple and compromised staple line integrity, which could in turn prolong surgery or cause postoperative anastomotic leak, hemorrhage, hemorrhage shock, additional surgical intervention or death." The Defendants also stated in the recall that they had identified the root cause and implemented corrective actions to address the issues.

5.4 On October 30, 2019, the FDA issued a Class One Device Recall for Defendants' Echelon Flex Endopath Staplers which were designed and manufactured for use in open or minimally invasive surgeries including thoracic and general surgeries including in patients undergoing laparoscopic longitudinal sleeve gastrectomy surgeries.

1 The recall was issued because the stapler may contain an out of specification component  
 2 within the jaw of the device, which could lead to malformed staples, which can compromise  
 3 staple line integrity.

4 5.5 Also, on March 3, 2019, the FDA issued a letter to medical providers warning  
 5 them that it was concerned about the safety of, and reliability of surgical staplers based on  
 6 increased amounts of adverse events involving surgical staplers that they had received. The  
 7 letter stated that the FDA's ongoing analysis of surgical staplers found that from January 1,  
 8 2011, to March 31, 2018, the FDA received over 41,000 individual medical device reports  
 9 for surgical staplers including: 366 deaths; over 9,000 serious injuries; and over 32,000  
 10 malfunctions. The letter also stated the FDA was considering reclassifying surgical staplers  
 11 from Class I devices to Class II devices due to the increasing adverse events reports they  
 12 were receiving involving surgical staplers. On October 8, 2021, the FDA issued an order  
 13 reclassifying surgical staplers and staples for internal use as a Class II device to help protect  
 14 patient safety and reduce the risk of adverse events associated with surgical staplers for  
 15 internal use. The reclassification of the surgical staplers and staples now requires premarket  
 16 notification and mandatory special controls to help mitigate known risks of the device.<sup>4</sup>

17 5.6 On information and belief, Plaintiff alleges the device subject to the recalls is  
 18 the same device used in her November 19, 2019, surgery and has also been identified as the  
 19 device that was used in her surgery by her medical providers and medical records.

20 5.7 The surgical stapler used in Plaintiff's November 19, 2019, surgery was: (1)  
 21 manufactured by the Defendants; (2) malfunctioned as a result of defects which rendered  
 22 the surgical stapler unreasonably dangerous (3) the defect existed at the time the stapler was  
 23 distributed by the Defendant as evidenced by the company's own recall notice and the FDA  
 24 recall notice; and (4) the defect was a producing cause of Plaintiff's injuries.

25 5.8 As a direct and proximate result of Defendants' negligence, manufacturing,  
 26 and design defects, Plaintiff has incurred losses and damages for personal injury, loss of

27 <sup>4</sup> [https://www.federalregister.gov/documents/2021/10/08/2021-22041/general-and-plastic-](https://www.federalregister.gov/documents/2021/10/08/2021-22041/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers)  
 28 [surgery-devices-reclassification-of-certain-surgical-staplers .](https://www.federalregister.gov/documents/2021/10/08/2021-22041/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers)

1 use, and enjoyment of life, the need for periodic medical examination and treatment, and  
 2 economic losses, including additional medical expenses, and the expenditure of time and  
 3 money, and will continue to incur losses and damages in the future.

4 5.9 Due to Defendants' negligence, failure to warn, manufacturing, and design  
 5 defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury,  
 6 plus punitive damages in a sum equal to a multiplier of damages determined to be adequate  
 7 by a jury.

8 WHEREFORE, Plaintiff requests relief as hereinafter provided.

9 **PLAINTIFF'S SECOND CAUSE OF ACTION**

10 **B. (STRICT LIABILITY DESIGN DEFECT)**

11 **Against all Defendants**

12 5.10 Plaintiff hereby incorporates the allegations contained in the preceding  
 13 paragraphs, as though fully set forth herein.

14 5.11 Plaintiff was harmed by Defendants' Echelon Flex Endopath Stapler, which  
 15 was distributed, manufactured, and sold by Defendants. Defendants' Echelon Flex  
 16 Endopath Staplers contained a design defect that made it unsafe to perform the function it  
 17 was intended to perform. Specifically, there was a design defect that would result in a  
 18 compromised staple line integrity and anastomotic leak despite proper utilization by a  
 19 surgeon.

20 5.12 As previously alleged, the Defendants' own recall notice and the FDA recall  
 21 notice identified that the product used in Plaintiff's November 19, 2019, surgery was  
 22 defectively designed. Specifically, the October 3, 2019, recall instituted by the Defendants  
 23 stated the recall was instituted because, *"the staplers may contain an out of specification*  
 24 *component within the jaw of the device, which could lead to malformed staples."* Plaintiff  
 25 alleges on information and belief that the defective design of the device used in Plaintiff's  
 26 surgery was a cause of the device to malfunction and lead to insufficient firing.

27 5.13 Additionally, on October 30, 2019, the FDA issued a Class One Device Recall  
 28 for Defendants' Endo-Surgery Intraluminal Staplers because, *"the staplers may contain an*

1 *out of specification component within the jaw of the device, which could lead to*  
2 *malformed staples.”* Plaintiff alleges, on information and belief, that the defective design  
3 of the device used in Plaintiff’s surgery was a cause of the device to malfunction and fail to  
4 completely form staples.

5 5.14 These recall notices have been terminated and the Defendants have resumed  
6 manufacturing, marketing, and selling the device that is the subject of Plaintiff’s claims.  
7 Presumably the design defect issues have been fixed, otherwise the Defendants would not  
8 have resumed the manufacturing, marketing, and selling of the device. This clearly indicates  
9 that a safer alternative design of the surgical stapler in question existed at the time of  
10 Plaintiff’s surgery. The design defect of the surgical stapler in question was a producing  
11 cause of Plaintiff’s injuries as incorporated in the preceding allegations. Had the Defendants  
12 implemented the safer alternative design prior to Plaintiff’s surgery it would have prevented  
13 or significantly reduced the risk of Plaintiff’s injuries and implementing the safer alternative  
14 design would not have substantially impaired the Defendants’ product’s utility. Likewise,  
15 Plaintiff asserts it was economically and technologically feasible for the Defendants to  
16 implement the safer alternative design prior to the time the device left the Defendants’  
17 control.

18 5.15 As a direct and proximate result of Defendants’ negligence, manufacturing,  
19 and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use  
20 and enjoyment of life, the need for periodic medical examination and treatment, and  
21 economic losses, including additional medical expenses, and the expenditure of time and  
22 money, and will continue to incur losses and damages in the future.

23 5.16 Due to Defendants’ negligence, failure to warn, manufacturing, and design  
24 defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury,  
25 plus punitive damages in a sum equal to a multiplier of damages determined to be adequate  
26 by a jury.

27 WHEREFORE, Plaintiff requests relief as hereinafter provided.  
28

**PLAINTIFF'S THIRD CAUSE OF ACTION**

**C. (STRICT LIABILITY-FAILURE TO WARN)  
Against all Defendants**

5.17 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.18 Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their Echelon Flex Endopath Staplers. Specifically, Defendants, and each of them, promoted the staplers as being safe while they knew about the risk of the staplers to malfunction and fail to completely form which could compromise staple line integrity. As a result, neither Plaintiff nor her surgeon knew of the risks of injury like the one Plaintiff suffered, prior to her surgery.

5.19 Defendants, and each of them, knew that the Echelon Flex Endopath Stapler posed a risk to patients when used as intended because, as stated in the recalls issued by the Defendants and the FDA both stated, *“the staplers may contain an out of specification component within the jaw of the device, which could lead to malformed staples.”*<sup>5</sup> Defendants have hidden the true risks of using the devices from surgeons and their patients.

5.20 Despite knowing about this defect, Defendants, and each of them, failed to warn potential surgeons or patients.

5.21 The Defendants continued to market, manufacture and sell the devices with the knowledge of the defects and potential risk of harm to patients and failed to inform potential patients and their physicians of these known defects and risks at the time of the sale of the devices. The failure to notify or warn the patients and their physicians of the defects and risks renders the devices unreasonably dangerous to the patient and their physicians. The failure to warn patients and their physicians of the defects and risks of the devices in question was a producing cause of Plaintiff's injuries.

---

<sup>5</sup> <https://www.fda.gov/medical-devices/medical-device-recalls/ethicon-recalls-echelon-flexm-endopathr-staplers-failure-completely-form-staples>

5.22 Plaintiff is unaware of any evidence that the Defendants warned Plaintiff's physicians of the defects and risks of the devices prior to Plaintiff's surgery. Plaintiff alleges on information and belief that had her physicians been warned or notified of the defects and risk of the devices prior to Plaintiff's surgery they would have not used the devices or subjected Plaintiff to the risks associated with using these devices. Plaintiff also alleges on information and belief that had her physicians been warned or notified of the defects and risk of the devices prior to Plaintiff's surgery they would have warned the Plaintiff prior to her surgery of the defects and risks associated with using the devices and Plaintiff would have been afforded the opportunity to make an informed decision on whether to proceed with the surgery given the risks.

5.23 As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

5.24 Due to Defendants' negligence, failure to warn, manufacturing, and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

#### **PLAINTIFF'S FOURTH CAUSE OF ACTION**

##### **D. (NEGLIGENCE) Against all Defendants**

5.25 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.26 Plaintiff's injuries associated with having numerous remedial surgeries and procedures as a result of the injuries she suffered in the November 19, 2019, surgery were all the result of Defendants' defective Echelon Flex Endopath Staplers.

1           5.27 At all times herein relevant, Defendants, and each of them, were in the  
2 business of designing, manufacturing, assembling, constructing, inspecting, and selling  
3 various types of medical devices, including the subject Echelon Flex Endopath Stapler.  
4 Defendants were further in the business of inspecting, maintaining, installing, and selling  
5 at retail to members of the public various types of medical devices designed and  
6 manufactured by Defendants, including the subject Echelon Flex Endopath Stapler.

7           5.28 At all times herein relevant, Defendants so negligently and carelessly  
8 designed, manufactured, constructed, assembled, inspected, and/or sold the subject Echelon  
9 Flex Endopath Stapler that it was dangerous and unsafe to be used for its intended uses.

10          5.29 Furthermore, at all times relevant to this action, Defendants so negligently  
11 and carelessly inspected, maintained, installed, and sold the subject Echelon Flex Endopath  
12 Staplers that it was dangerous and unsafe for its intended uses.

13          5.30 Defendants had a duty to exercise reasonable care, and to comply with the  
14 existing standards of care, in their preparation, design, research, development, manufacture,  
15 inspection, labeling, marketing, promotion, and sale of the subject Echelon Flex Endopath  
16 Staplers device that was used on Plaintiff.

17          5.31 At all times herein relevant, Defendants knew or reasonably should have  
18 known that the subject Echelon Flex Endopath Staplers was unreasonably dangerous and  
19 defective when used as directed and designed, including but not limited to its failure to  
20 create staple lines leading to anastomotic leaks and other complications and injuries.

21          5.32 Based on what Defendants knew or should have known as described above,  
22 Defendants deviated from the standard of care and were negligent in introducing the  
23 Echelon Flex Endopath Stapler, which was unreasonably dangerous and defective when  
24 used as directed and designed, into the stream of commerce.

25          5.33 Further, Defendants were negligent for not providing sufficient notice or  
26 warnings of the risks associated with using the Echelon Flex Endopath Stapler, including  
27 the risks associated with malfunction.



1 DATED this 19<sup>th</sup> day of November, 2021.

2 DALIMONTE RUEB & STOLLER

3 /s/ Paul L. Stoller

4 Paul L. Stoller (No. 016773)

Ashley Crowell (No. 027289)

5 2425 E. Camelback Rd., Suite 500

6 Phoenix, AZ 85016

602-888-2807 (phone)

7 602-530-8500 (fax)

[paul@drlawllp.com](mailto:paul@drlawllp.com)

8 [ashley@drlawllp.com](mailto:ashley@drlawllp.com)

9 and

10 **MARTIN BAUGHMAN, PLLC**

11 /s/ Ben C. Martin

12 Ben C. Martin (Texas Bar No. 13052400)

(admission application forthcoming)

13 Kolter C. McKenzie (Texas Bar No. 24067762)

(admission application forthcoming)

14 3141 Hood Street, Suite 600

Dallas, Texas 75219

(214) 761-6614

15 Facsimile: (214) 744-7590

16 [bmartin@martinbaughman.com](mailto:bmartin@martinbaughman.com)

[kmckenzie@martinbaughman.com](mailto:kmckenzie@martinbaughman.com)

17 *Attorneys for Plaintiff*

27 DALIMONTE RUEB  
STOLLER, LLP

28 PHOENIX, AZ